

JAN 29 2001

**510(k) Summary**

**SUBMITTER:** Stöckert Instrumente GmbH  
Division of Sorin Biomedica  
Lilienthalalle 5-7  
D-80939 Munich Germany

**APPLICANT:** COBE Cardiovascular, Inc.  
Division of Sorin Biomedica  
14401 W. 65<sup>th</sup> Way  
Arvada, Colorado 80004-3599 USA

**CONTACT PERSON:** Barbara Watson  
Regulatory Affairs Specialist  
COBE Cardiovascular, Inc.  
Arvada, Colorado USA  
Phone: (303) 467-6018  
Fax: (303) 467-6429

**DATE PREPARED:** November 13, 2000

**DEVICE TRADE NAME:** Stöckert A272-40 Pediatric Aortic Cannulae, 12 Fr

**COMMON/USUAL NAME:** Cardiovascular Aortic Cannulae

**CLASSIFICATION NAME:** Cardiopulmonary Bypass Vascular Catheter, Cannula or Tubing

**PREDICATE DEVICE:** Baxter Research Medical Inc. Pediatric Aortic Cannula  
Non-Wire Reinforced with Curved Tip, Suture Bump, Vent Plug

**DEVICE DESCRIPTION:**

The Stöckert A272-40 Pediatric Aortic Cannulae, 12 Fr size, is a sterile, non-pyrogenic device, for single use only, and not to be resterilized by the user. The device is a wire reinforced aortic cannula. It is intended to be used for cannulation of the ascending aorta during cardiopulmonary bypass surgery.

The Stöckert A272-40 Pediatric Aortic Cannulae are composed of two components, the cannula tube and the curved tip. Encapsulated within the cannulae outer wall is a helically wound stainless steel wire which allows the cannula tube to resist kinking. The length of the device is 22 cm.

**INDICATIONS FOR USE**

The Stöckert A272-40 Pediatric Aortic Cannulae are intended to be used for cannulating the ascending aorta during cardiopulmonary surgery for periods of up to six hours.

#### STATEMENT OF TECHNICAL CHARACTERISTICS COMPARISON

The Stöckert A272-40 Pediatric Aortic Cannula, 12 Fr size, is substantially equivalent to the 12 Fr size of the Baxter Research Medical Inc. Pediatric Aortic Cannula, Non-Wire Reinforced, with Curved Tip, Suture Bump, and Vent Plug. The devices are both aortic cannulae with curved tip on the distal end and without a connector on the proximal end. The 12 Fr size of the Stöckert Pediatric Aortic Cannulae is 22 cm in length and accepts a 3/16 -1/4" connector. The 12 Fr size of the Baxter RMI Pediatric Aortic Cannulae is 18 cm in length and accepts a 1/4" connector.

The following tests were performed to demonstrate substantial equivalency of the Stöckert A272-40 Pediatric Aortic Cannulae, 12 Fr size, to the 12 Fr size of the Baxter Research Medical Inc. Pediatric Aortic Cannula:

1. Pressure Drop
2. Blood Trauma
3. Leak
4. Kink Resistance
5. Bond Strength
6. Dimensional Inspection Post-sterilization and Post-aging



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

JAN 29 2001

COBE Cardiovascular, Inc.  
Division of SORIN BIOMEDICA  
c/o Ms. Barbara A. Watson  
Regulatory Affairs Specialist  
14401 W. 65<sup>th</sup> Way  
Arvada, CO 80004-3599

Re: K002273  
Trade Name: Stöckert A272-40 Pediatric Aortic Cannulae, 12 Fr  
Regulatory Class: II (two)  
Product Code: DWF  
Dated: November 13, 2000  
Received: November 14, 2000

Dear Ms. Watson:

We have reviewed your Section 510(k) notification of intent to ~~market~~ the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

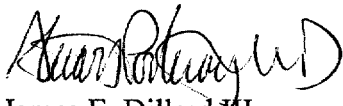
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

Page 2 – Ms. Barbara A. Watson

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4648. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsma/dsmamain.html>".

Sincerely yours,

  
for James E. Dillard III  
Director  
Division of Cardiovascular and  
Respiratory Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

## Indications For Use

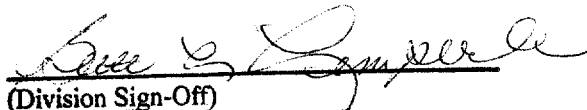
510(k) Number (If known): K002273

Device Name:

Stöckert A272-40 Pediatric Aortic Cannulae, 12 Fr

Indications For Use:

The Stöckert A272-40 Pediatric Aortic Cannula, 12 Fr, is intended to be used for cannulating the ascending aorta during cardiopulmonary surgery for periods of up to six hours.



(Division Sign-Off)  
Division of Cardiovascular, Respiratory,  
and Neurological Devices

510(k) Number K002273


PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE  
IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ☒  
(Per 21 CFR 801.109)

OR

Over-The-Counter Use ☐

 1-26-1  
Division of Cardiovascular & Respiratory Devices  
510(k) Number K002273